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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-417]

Schedules of Controlled Substances: Placement of UR-144, XLR11, and AKB48 into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle UR-144, XLR11, or AKB48.

DATES: Effective: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II.

The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812.

The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.” The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA, 28 CFR part 0, appendix to subpart R.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);¹ or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated by the former DEA Administrator on her own motion and is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled

¹ As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to “Secretary” have been replaced with “Assistant Secretary.”

substances on any person who handles, or proposes to handle, UR-144, XLR11, or AKB48.

Background

On April 12, 2013, the DEA published a notice of intent to temporarily place (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoropentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) into schedule I pursuant to the temporary scheduling provisions of the CSA. 78 FR 21858. On May 16, 2013, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these three synthetic cannabinoids into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 78 FR 28735. That final order was effective on the date of publication, and was based on findings by the DEA that the temporary scheduling of these three synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Section 201(h)(2) of the CSA requires that the temporary control of these substances expire two years from the effective date of the scheduling order, or on May 15, 2015. 21 U.S.C. 811(h)(2). However, the CSA also provides that the temporary scheduling may be extended for up to one year during the pendency of proceedings under 21 U.S.C. 811(a)(1). *Id.* Accordingly, on May 14, 2015, the DEA published a notice of proposed rulemaking (NPRM) to permanently control UR-144, XLR11, and AKB48 in schedule I of the CSA. 80 FR 27611. Specifically, the DEA proposed to add these substances to 21 CFR 1308.11(g), cannabimimetic agents. On May 15, 2015, the DEA extended the temporary scheduling of UR-144, XLR11, and AKB48 by one year, until

May 15, 2016. 80 FR 27854. On March 22, 2016, the DEA published a corrected notice of proposed rulemaking, proposing the placement of these substances as hallucinogenic substances under 21 CFR 1308.11(d), and providing an opportunity to comment on this proposed change. 81 FR 15188.

DEA and HHS Eight Factor Analyses

On May 11, 2015, the HHS provided the DEA with three scientific and medical evaluation documents prepared by the FDA entitled “Basis for the recommendation to place 1-pentyl-1H-indol-3-yl-2,2,3,3-tetramethylcyclopropyl methanone (UR-144) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” “Basis for the recommendation to place 1-(5-fluoro-pentyl)-1H-indol-3-yl 2,2,3,3-tetramethylcyclopropyl methanone (XLR11) and its salts in Schedule 1 of the Controlled Substances Act (CSA);” and “Basis for the recommendation to place (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide) (AKB48; APINACA) and its salts in Schedule 1 of the Controlled Substances Act (CSA).” After considering the eight factors in 21 U.S.C. 811(c), including consideration of each substance’s abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that UR-144, XLR11, and AKB48 be controlled in schedule I of the CSA. In response, the DEA conducted its own eight-factor analysis of UR-144, XLR11, and AKB48. The DEA and HHS analyses are available in their entirety in the public docket for this rule (DEA-2015-0007 / agency Docket Number DEA-417) at <http://www.regulations.gov> under “Supporting Documents.”

Determination to Schedule UR-144, XLR11, and AKB48

After a review of the available data, including the scientific and medical evaluations and the scheduling recommendations from the HHS, the DEA published an NPRM entitled “Schedules of Controlled Substances: Placement of UR-144, XLR11, and AKB48 into Schedule I,” proposing to control UR-144, XLR11, and AKB48 in schedule I of the CSA. 80 FR 27611, May 14, 2015. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with the DEA regulations on or before June 15, 2015. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before June 15, 2015.

Comments Received

The DEA received three comments on the proposed rule to control UR-144, XLR11, and AKB48 in schedule I of the CSA. One commenter stated that the “longwinded and unnecessarily difficult names of the chemical substances mentioned” were offensive and that they should be changed “in the name of a truly transparent government.” A second commenter questioned the safety of methadone, and the third commenter opposed the control of UR-144, XLR11, and AKB48.

Two comments were received in response to the publication of the NPRM correction, for which comments were to be limited to addressing the change in the proposed placement in the CFR for the substances as hallucinogenic substances rather than cannabimimetic agents. Both comments addressed whether or not these substances should be scheduled, with one commenter supporting scheduling and the other opposing. Thus, both comments were outside the scope for which comments were being accepted.

Comments Received in Response to NPRM.

Request to Shorten Chemical Names. One commenter stated that the chemical names for UR-144, XLR11, and AKB48 were unnecessarily difficult to understand and requested they be shortened.

DEA Response: In order to ensure the public is aware of the specific substances that were proposed to be controlled, and are controlled, as schedule I substances, the DEA used both the standard chemical names for UR-144, XLR11, and AKB48 and the common street level names that correspond to each substance. All names known by the DEA for UR-144, XLR11, and AKB48 were provided in the NPRM, the NPRM correction, and in this final rule. In addition, to prevent any confusion with nomenclature or other references to these substances, the DEA also used shortened names for these substances, including UR-144, XLR11, 5-fluoro-UR-144, AKB48, and APINACA. Each of the names provided in the NPRM, the NPRM correction, and this final rule are commonly accepted identifiers for the three substances.

Comment Regarding Methadone. One commenter stated that methadone is very dangerous to use, especially with the consumption of alcohol.

DEA Response: Methadone is a schedule II synthetic opioid and is not affected by this rule.

Request Not to Control UR-144, XLR11, and AKB48. One commenter opposed controlling UR-144, XLR11, and AKB48 stating “there is no reason to have this law.”

DEA Response: As outlined in detail in the HHS and DEA eight-factor analyses, there is substantial evidence to support control of UR-144, XLR11, and AKB48 in schedule I of the CSA.

The use of UR-144, XLR11, and/or AKB48 has been linked to serious adverse effects including vomiting, nausea, anxiety, agitation, seizures, hallucinations, tachycardia, and stroke, which require visits to emergency facilities. In addition to the serious adverse effects, the misuse and abuse of UR-144, XLR11, and/or AKB48 has been shown to result in death. As reported by the National Forensic Laboratory Information System (NFLIS), there have been over 46,000 reports for UR-144, XLR11, and AKB48 since 2011 in at least 44 states. As determined by the HHS, there is no accepted medical use for UR-144, XLR11, and AKB48.

Scheduling Conclusion

After consideration of the relevant matter presented as a result of public comment, the scientific and medical evaluations and accompanying recommendations of the HHS, and its own eight-factor analyses, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of UR-144, XLR11, and AKB48. As such, the DEA is permanently scheduling UR-144, XLR11, and AKB48 as controlled substances under the CSA.²

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analyses and recommendations of the Assistant Secretary for HHS and review of all other

² UR-144, XLR11, and AKB48 were initially proposed to be scheduled under § 1308.11(g). However, they do not meet the structural requirement for “cannabimimetic agents.” Consistent with the analysis set forth in the DEA’s 8-factor analysis, on March 22, 2016, the DEA published a corrected notice of proposed rulemaking, with opportunity for comment, proposing the placement of these substances as hallucinogenic substances under 21 CFR 1308.11(d). 81 FR 15188. The substances are being placed under § 1308.11(d), hallucinogenic substances, under this final rule.

available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) have a high potential for abuse that is comparable to other schedule I substances such as delta-9-tetrahydrocannabinol (Δ^9 -THC) and JWH-018;

(2) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) under medical supervision.

Based on these findings, the Administrator of the DEA concludes that (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) including their salts, isomers and salts of isomers, whenever the existence of such salts,

isomers, and salts of isomers is possible, warrant control in schedule I of the CSA.

21 U.S.C. 812(b)(1).

Requirements for Handling UR-144, XLR11, and AKB48

UR-144, XLR11, and AKB48 are currently scheduled on a temporary basis in schedule I³ and therefore continue to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research and conduct of instructional activities or chemical analysis, and possession of schedule I controlled substances, including those listed below. These controls will continue on a permanent basis:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) UR-144, XLR11, or AKB48, or who desires to handle UR-144, XLR11, or AKB48 must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.
2. *Disposal of Stocks.* UR-144, XLR11, and AKB 48 must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.
3. *Security.* UR-144, XLR11, and AKB48 continue to be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71–1301.93.

³ UR-144, XLR11, and AKB48 are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 80 FR 27854, May 15, 2016.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of UR-144, XLR11, and AKB48 must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture UR-144, XLR11, or AKB48 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant required to keep records and who possesses any quantity of UR-144, XLR11, or AKB48 is required to maintain an inventory of all stocks of UR-144, XLR11, and/or AKB48 on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding UR-144, XLR11, and/or AKB48 to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes UR-144, XLR11, and/or AKB48 must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of UR-144, XLR11, and AKB48 must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving UR-144, XLR11, or AKB48 not authorized by, or in violation of, the CSA or its implementing regulations continues to be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires that rules enacted in accordance with the procedures of 5 U.S.C. 553 to be effective not less than 30 days after publication of the proposed rule. 5 U.S.C. 553(d). However, the APA provides three exceptions for when an agency may make a rule effective sooner than 30 days after publication, including if the agency finds for good cause why the rule should be effective sooner and publishes those reasons with the rule. 5 U.S.C. 553(d)(3). The DEA finds that there is good cause for this scheduling action to be immediately effective upon publication. A delay in the effective date is unnecessary and contrary to the public interest. It is unnecessary because UR-144, XLR11, and AKB48 are already controlled under 21 USC 811(h). Additionally, a delay in the effective date could potentially temporarily eliminate these substances from being controlled, thereby resulting in an imminent hazard to the public safety. As noted above, the use of UR-144, XLR11, and/or AKB48 has been linked to serious adverse effects including vomiting, nausea, anxiety, agitation, seizures, hallucinations, tachycardia, and stroke, which require visits to emergency facilities. In addition to the serious adverse effects, the misuse and abuse of UR-144, XLR11, and/or AKB48 has been shown to result in death.

Executive Orders 12866 and 13563, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On May 16, 2013, the DEA published a final order amending 21 CFR 1308.11(h) to temporarily place these three synthetic cannabinoids into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 78 FR 28735. On May 15, 2015, the DEA published a final order extending the temporary placement of these substances in schedule I of the CSA for up to one year pursuant to 21 U.S.C. 811(h)(2). 80 FR 27854. Accordingly, all entities that currently handle or plan to handle these synthetic cannabinoids are estimated to have already established and implemented the systems and processes required to handle UR-144, XLR11, and AKB48. Therefore, the DEA anticipates that this rule will impose minimal or no economic impact on businesses that currently handle UR-144, XLR11, or AKB48 for lawful purposes. This estimate applies to entities large and small. Accordingly, the DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action will not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in

any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: “an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets.” However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. In § 1308.11:

a. Add paragraphs (d) (48) through (50); and

b. Remove paragraphs (h)(1) through (3) and redesignate paragraphs (h)(4) through (25) as paragraphs (h)(1) through (22), respectively.

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(48) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144).....(7144)

(49) [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11).....(7011)

(50) *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48).....(7048)

* * * * *

Dated: May 6, 2016

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-11204 Filed: 5/10/2016 8:45 am; Publication Date: 5/11/2016]